GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

STARRED QUESTION NO:332
ANSWERED ON:06.09.2007
OUTSOURCING OF PRODUCTION OF DRUGS BY MAJOR BRAND COMPANIES
Rao Shri Kavuru Samba Siva

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the number of major brand companies outsourcing production of drugs to lesser-known pharma manufacturing units and the quantity and value of such drugs produced each year during the last three years;

(b) the extent to which the big companies misused the provision of getting the drugs exempted from price control through outsourcing during the above period;

(c) whether the Government proposes to initiate measures to check such misuse by fixing the ceiling price of all the medicines; and

(d) if so, the details thereof?

Answer

THE MINISTER OF CHEMICALS AND FERTILIZERS & MINISTER OF STEEL (SHRI RAM VILAS PASWAN)

(a) to (d) : A Statement is laid on the Table of the House.

STATEMENT REFERRED IN REPLY TO PARTS (a) to (d) OF THE LOK SABHA STARRED QUESTION NO. 332 FOR ANSWER ON 6.9.2007 ON THE SUBJECT OF OUTSOURCING OF PRODUCTION OF DRUGS BY MAJOR BRAND COMPANIES

(a) to (d) As per the information received from Pharmaceutical Industry sources , the outsourcing activity is being carried out routinely in pharmaceutical industry. It is used to meet short term needs for capacity, special regulatory requirement and product specific technology needs which benefit the smaller units by making them economically viable through use of their idle capacity. However, neither the government nor the industry associations are maintaining any comprehensive data on outsourcing. Compilation of such data is time consuming and costly because several hundred units are engaged in this activity, and the product mix is not constant.

The 74 bulk drugs specified in the First Schedule of the Drugs (Prices Control) Order, 1995 (DPCO,95) and the formulations based thereon are under price control and their prices are fixed/revised by the National Pharmaceutical Pricing Authority (NPPA) in accordance with the provisions of Para 7 of the DPCO, 95. Under Para 8 of DPCO, 95 non ceiling Price is fixed which is formulation specific and company specific. Under Para 9 of DPCO, 95 Ceiling Price is fixed which is applicable to all manufacturers.

Exemption from Price Control under the DPCO, 95 is available on the basis of indigenous R&D and new drug delivery system. Exemption from Price Control under Para 8 of the DPCO, 95 is also available to SSI Pharma units subject to fulfilling certain conditions specified in order S.O. No. 134(E) dated 02.03.1995 issued under Para 25 of the DPCO, 95

Prices of non-Scheduled formulations are fixed by the manufacturers themselves keeping in view the various factors like cost of production, marketing/selling expenses, R&D expenses, trade commission, market competition, product innovation, product quality etc. The Government takes corrective measure where the public interest is found to be adversely affected.

NPPA has initiated more intensive scrutiny of application for non-ceiling price with a view to increase the coverage of scheduled formulations packs through ceiling prices. Accordingly, because of the conscious effort by NPPA in this direction the percentage of ceiling prices fixed have substantially increased to around 70% (711 packs out of 1020 scheduled formulation packs) for which prices were fixed during 2006-07, as against earlier level of around 55% (182 packs out of 332 scheduled formulation packs) for which prices were fixed during 2004-05. This effort of the NPPA also resulted in achieving better enforcement and compliance with the provisions of DPCO, 1995 and Govt. policies in this regard.